Appl. No. : 10/630,629 Filed : July 29, 2003

### **REMARKS**

## A. <u>Disposition of Claims</u>

Claims 1-20 are pending in this application. Claims 6-20 have been withdrawn from consideration. Claims 1-5 and 13-15 have been amended to define P. falciparum erythrocyte binding protein-2 (EBP2) as the claimed paralogue of EBA-175, the amino acid sequence of which is SEQ ID NO:1, and P. falciparum erythrocyte binding protein-2 (EBP2) Region II (RII)—possessing EBPs as the claimed family by virtue of possessing the ligand binding domain thereof, the amino acid sequence of which is amino acids 147 to 762 of SEQ ID NO:1. Support for the amendment is found throughout the patent specification, for example, page 5, ¶¶ 1 and 2 (P. falciparum erythrocyte binding protein-2 (EBP2), the amino acid sequence of which is SEQ ID NO:1), and page 34, ¶ 1 (P. falciparum erythrocyte binding protein-2 (EBP2) Region II (RII), the amino acid sequence of which is amino acids 147 to 762 of SEQ ID NO:1). Because the claim term is defined in the specification, the amendment adding the definition to the claims is purely cosmetic and thus made for reasons unrelated to patentability. The paragraph on page 32 has been amended to conform to MPEP § 601.01 VII Hyperlinks and Other Forms of Browser-Executable Code in the Specification. No new matter has been added. Reexamination and reconsideration of the application, as amended, are respectfully requested.

## B. Rejoinder of Claims

The Examiner required restriction between product and process claims. Applicant elected claims directed to the product with the understanding that upon allowance of the product claims, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104.

# C. Compliance with 35 USC 112/1 written description

The issue is whether Claims 1, 3, and 4 are in compliance with 35 USC 112/1 as meeting the written description requirement. These claims had referred to a "paralogue of EBA-175 polypeptide sequence". The definition of a paralogue given in the patent specification (page 13, ¶ 1) indicates that the said term "paralogue" summarizes all sequences which are "assumed to have originated from a single ancestral gene".

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The claimed embodiment solves the problem in the prior art of the need to identify alternative Plasmodium falciparum erythrocyte-binding proteins further to erythrocyte binding antigen EBA-175 that mediate invasion of erythrocytes by P. falciparum. The inventors identified a family of erythrocyte binding proteins (EBPs) paralogous to EBA-175 that solves this problem. One of the family members is EBP2 (SEQ ID NO:1). Recognition of erythrocytes by Plasmodium species depends on Region II (RII) of the paralogous EBA-175 (Sim et al., Science 264:1941 (1994), of record). Similarly, the erythrocyte binding of EBP2 is mediated by RII (page 14, penultimate line – page 17, last line).

Claims 1-5 and 13-15 have been amended to define <u>P. falciparum erythrocyte binding protein-2 (EBP2)</u> as the claimed paralogue of EBA-175, the amino acid sequence of which is <u>SEQ ID NO:1</u>, and <u>P. falciparum erythrocyte binding protein-2 (EBP2) Region II (RII) – possessing EBPs as the claimed family by virtue of possessing the ligand binding domain thereof, the amino acid sequence of which is amino acids 147 to 762 of SEQ ID NO:1. The latter (<u>P. falciparum erythrocyte binding protein-2 (EBP2)</u> Region II (RII) –possessing EBPs) defines a genus that includes the former (<u>P. falciparum erythrocyte binding protein-2 (EBP2)</u>) as a species encompassed within that genus. A written description of the claimed genus is satisfied through sufficient description of a representative number of species because the species must encode the ligand binding domain and thus they fairly represent the variation within the entire genus because there is virtually no variation in this regard with respect to the ligand binding domain. The conclusion is the claims are in compliance with 35 USC 112/1 as meeting the written description requirement.</u>

### D. Compliance with 35 USC 112/2

The issue is whether Claims 1-5 are in compliance with 35 USC 112/2 as being definite for recitation of the expression "EBA-175" for being an abbreviation of a term that lacks antecedent basis in the claims. This expression has been canceled, and all other abbreviations have been spelled out so that there is exact antecedent basis for all abbreviations in the claims. The conclusion is the claims are in compliance with 35 USC 112/2 as being definite.

## E. Compliance with 35 USC 102(b)

The issue is whether Claims 1, 3, and 4 are in compliance with 35 USC 102(b) or anticipated by Sim et al. (USP 5,849,306 issued December 15, 1998). The rule according to

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MPEP 2131 is that to anticipate a claim, the reference must teach every element of the claim. The Sim et al. patent describes erythrocyte binding proteins. Nevertheless, the element of <u>P. falciparum erythrocyte binding protein-2 (EBP2)</u>, the amino acid sequence of which is <u>SEQ ID NO:1</u>, and <u>P. falciparum erythrocyte binding protein-2 (EBP2) Region II (RII), the amino acid sequence of which is amino acids 147 to 762 of SEQ ID NO:1</u> are missing from the Sim et al. patent. Because the Sim et al. patent does not teach these elements, a case for anticipation fails, ergo the claims are in compliance with 35 USC 102(b).

### **CONCLUSION**

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Respectfully submitted,

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**AMEND** 

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